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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,362	02/16/2000	David Clive Williams	49592 (1878)	6693

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EXAMINER

FORD, JOHN M

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 04/03/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/506362

Applicant(s)

Williams et al

Examiner

J. M. Ford

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on January 7, 2002
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 20 -- 32 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 20 -- 31 is/are rejected.
- ☒ Claim(s) 32 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☒ Other Exhibit A

Office Action Summary

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This application has been revived. The amendment of Jan. 7, 2002, is noted.

The claims in the application are claims 20--32.

It is requested that "for inducing apoptosis" be removed from claim 20. The expression is considered non-specific, as noted in the Office Action of April 18, 2001.

The Utility needs to relate to the real world of Commerce, as noted.

Claim 27 is rejected under 35 U.S.C. 112, 1st paragraph as not relating to the real world of Commerce.

Claims 20--25 could be allowed if the wording of claim 20 was ~~amended~~ as requested.

Claim 20 is rejected under 35 U.S.C. 112, 2nd paragraph as it presently reads.

The Utility in claim 26 is too broadly ~~stated~~ and is rejected under 35 U.S.C. 112, 1st paragraph.

Two utility statements, neither allowable are found in the claims. See claim 29.

Applicants need to elect one (See MPEP 806.05 (h)) and make the statement specific.

Claims 29, 30 and 31 are rejected under 35 U.S.C. 112 1st paragraph, as the treatment of all tumors could not be considered adequately supported with sufficient representative in this specification.

The treatment of all tumors cannot be acceptable as one specific utility. The recent utility guidelines set by USPTO require applicants to meet the requirements as stated in Brenner v. Manson in 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist is currently available form" similar is the "immediate benefit to the public:

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standard set forth in the concurring opinion of *In re Hartop*, 135 USPQ 419 is whether the invention has been brought to such perfection as to be capable of practical employment. This language is echoed in *Bindra vs Kelly*, 206 USPQ 570.

MPEP 806.05 (h), as does 37 CFR 1.475 and PCT Rule 13.2, provides for one method of use to be examined with the elected compounds. A broad disclosure of Utility as in the cited claim 7 cannot be deemed in compliance with 35 U.S.C. 112, first paragraph.

The U.S.P.T.O. has amended the guidelines to clarify "specific utility." The court focused on the fact that the applicant failed to identify a "Specific utility" in *Brenner v. Manson*.

This requirement of one specific utility is also in compliance with 37 CFR 1.475; the Unity of Invention Practice in International Applications and National Phase Applications under 35 U.S.C. 371, and PCT Rule 13.2.

Therefore, applicants should limit the method claims to a sole "specific utility".

Applicants need to pick one believable utility for the claims.

Examples of generalized and vague assertions of utility which do not meet the disclosure requirement of 35 U.S.C. 112 are: statement that a product is a pharmaceutical", "therapeutic agent", or has "biological utility", or is "an intermediate to make a drug", citing, respectively, *In re Diedrich* (CCPA 1963) 318 F2d 946, 138 USPQ 128; *In re Lorenz et al.* (CCPA 1962) 305 F2d 875, 134 USPQ 312 and *Ex parte Brokman et al.* (POBA 1959) 127 USPQ 57; *In re Kirt et al.* (CCPA 1967) 153 USPQ 48; and *In re Joly et al.* (CCPA 1967) 376 F2d 906, 153 USPQ 45.

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A disclosure that the claimed compounds can be used for “technical and pharmaceutical purposes” does not meet the requirements of 35 U.S.C. 112, In re Diedrich (CCPA 1963) 318 F.2d 946, 138 USPQ 128.

The expressions “biological activity” and “biological properties” are too nebulous to meet the requirement of 35 U.S.C. 112. In re Kirk et al. (CCPA 1967) 376 F.2d 936, 153 USPQ 48. Same, “good effects against a very wide range of insects”. In re Lorenze et al. (CCPA 1962) 305 F.2d 875, 134 USPQ 312.

The “how to use” requirements of 35 U.S.C. 112 are not met by disclosing only a pharmacological activity of the claimed compounds if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Driedrich (CCPA 1963) 318 F.2d 946, 138 USPQ 128; In re Gardner et al. (CCPA 1970) 427 F.2d 786, 166 USPQ 138. Thus, where the claimed compounds are not structurally similar to known compounds having the same activity and their pharmaceutical properties could not be predicted their chemical structure, a disclosure that they possess a particular activity against a pathological organism (antitubercular activity) may not suffice as a description of how to use as required by 35 U.S.C. 112. In re Moureu et al. (CCPA 1965) 345 F.2d 595, 145 USPQ 452.

Statements of utility which relate to or imply the treatment of a disease are subject to closer scrutiny. *Ex parte Moore et al.* (POBA 1960) 128 USPQ 8. Thus, when the disclosed utility is the production of a physiological response, e.g. antidepressant effect, the dosage

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effective to achieve this response in host, whether human or animal, must be disclosed. In re Garner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138.

The fact that structurally unrelated prior art compounds have been used to protect the liver from the effects of hepatitis does not render obvious to one skilled in the art how to use a novel compound disclosed to “assist the liver Function in hepatic disturbances and can, therefore, be used as medicament in humans and veterinary medicine”. In re Schmidt et al. (CCPA 1967) 377 F2d 639, 153 USPQ 640.

A specification which discloses only one mode of administration of medicinal for the purpose of effecting a modification in a body function does not provide support for a claim not limited to that specific mode. Ex parte Proctor (POBA 1966) 158 USPQ 677.

A method claim which designates amount of an ingredient of a claimed method as “an effective amount” is too broad and indefinite if it does not designate the intended effect; Ex parte Dobson et al. (POBA 1969) 165 USPQ 29. In re Fedriken, 102 USPQ 35, (CCPA 1954) A cancer or a tumor, or a solid tumor is not specific to one disease.

Issentstead v. Watson, (DCDC 1957) 157 F Supp. 7, 115 USPQ 408 and Schindler v. Comr. of Pats. (DCDC 1967) 269. F. Supp 630, 155 USPQ 838. Note where an application discloses therapeutic effect on humans or a cure for a human disease as the utility of a claimed process, the District Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. Radoev v. Brenner, Ferguson, (POBA 1957) 117 USPQ 229.

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Where utility is based on the alleged enhancement of activity of known medicinals. The CCPA upheld the Examiner's requirement that the applicant submit evidence which substantiated the allegation, unless one skilled in the art would accept them as obviously valid and correct. In re Novak et al., (CCPA 1962) 306 F2d 924, 134 USPQ 335.

The Board of Appeals and the CPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of human use and require proof thereof when such use is a medical nature for the treatment of a serious disease, such as cancer. *Ex parte Moore et al.*, (POBA 1960) 128 USPQ 8; In re Citron (CCPA 1964) 325 F2d 248, 139 USPQ 516; In re Hartop et al., (CCPA 1962) 311 F2d. 135 USPQ 419.

The Supreme Court declined to express a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. pats. V. Manson, (USC 1966) 383 U.S. 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use-testing, reasoning the patent system is related to the world of commerce, rather than the realm of philosophy ibid., 148 USPQ at 696.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and by the American Medical Association

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Council on Pharmacy, the Board noting that remission, not cures, were alleged in the specification. Ex parte Timmis, (POBA 1959) 123 USPQ 581. Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims directed to a method of treating seven cancers. In re Butting, (CCPA 1969) 418 F2d, 163 USPQ 689.

MPEP 806.05 (h) indicates that claims 11, 12, 19 and 20 may be held withdrawn, altogether, if they are not limited to one provable utility.

Claim 32 is a list of specific species in one claim. The determination of patentability is very time consuming in a instance of that type as each species has be considered separately. The Examiner is not given the time to search each species individually.

No acceptable drawings are found. Perhaps the drawings should just be canceled.

In regard to a claim of the type of claim 32, cancel “as defined above” and put on “or” before the last species.

Claim 31 cannot be allowed, as it is dependent on a rejected claim.

Claim 30 cannot be allowed as it is not directed to a specific single cancer (elected) and the form modified, note the objection to claim 32.

Claim 29 cannot be allowed, as it is not directed to one specific cancer and elected.

Claim 28 cannot be allowed as it is dependent on a rejected claim.

Claim 27 cannot be allowed as “inducing apoptosis” cannot be considered a real would utility and the form of the claim needs adjusted, see the objection to claim 32.

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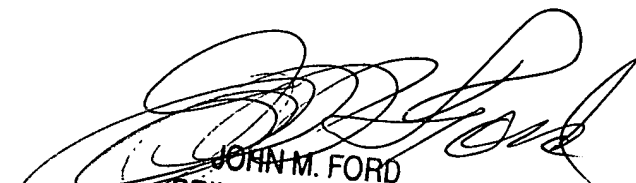
Claim 26 cannot be allowed as the “inducing apoptosis” cannot be considered an acceptable utility.

Claim 25 needs the adjustment noted in regard to claim 32.

In regard to claim 25, see Commissioner Wahl’s memo (Exhibit A) enclosed.

J. M. Ford:jmr

March 25, 2002


JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624